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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20.03.2001
C(2001) 767

NOT FOR PUBLICATION

COMMISSION DECISION

of 20.03.2001

concerning the transfer of the marketing authorisation for the medicinal product for human use
"CETROTIDE - Cetrorelix (as acetate)"

(Text with EEA relevance)

ONLY THE GERMAN AND ENGLISH TEXT ARE AUTHENTIC

COMMISSION DECISION

of 20.03.2001

concerning the transfer of the marketing authorisation for the medicinal product for human use
"CETROTIDE - Cetrorelix (as acetate)"

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products,[1] as amended by Commission Regulation (EC) No 649/98,[2] and in particular Article 10(1) and (2) thereof,

Having regard to Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93,[3] and in particular Article 6 thereof,

Having regard to the application for the transfer of the marketing authorisation for the medicinal product **"CETROTIDE - Cetrorelix (as acetate)"** entered in the Community register of medicinal products under No(s) EU/1/99/100/001-003, submitted under Article 3 of that Regulation on 23 December 2000 by ASTA Medica Aktiengesellschaft, Deutschland,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

(1) Changing the name of the holder of the marketing authorisation is an administrative operation and does not affect the scientific characteristics of the medicinal product that has already been authorised and which meets the requirements of Council Directives 65/65/EEC,[4] 75/318/EEC[5] and 75/319/EEC,[6] as last amended by Directive 93/39/EEC.[7]

(2) It is necessary to set a cut-off date by which all the procedures resulting from the transfer of a marketing authorisation must be completed,

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1 OJ L 214, 24. 8. 1993, p. 1.
2 OJ L 88, 24.3.1998, p. 7.
3 OJ L 286, 8.11.96, p. 6.
4 OJ 22, 9.2.1965, p. 369/65.
5 OJ L 147, 9.6.1975, p. 1.
6 OJ L 147, 9.6.1975, p. 13.
7 OJ L 214, 24.8.1993, p. 22.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation referred to in Article 3 of Regulation (EEC) No 2309/93, issued on 13 April 1999 to ASTA Medica Aktiengesellschaft, Deutschland, in respect of the medicinal product **"CETROTIDE - Cetrorelix (as acetate)"** entered in the Community register of medicinal products under No(s) EU/1/99/100/001-003, is hereby transferred to Ares Serono (Europe) Ltd.

Article 2

Decision C(1999) 939 of 13 April 1999 is hereby amended as follows:

1. Annex I - summary of product characteristics

-Point 7: name and address of the holder of the marketing authorisation: Ares Serono (Europe) Ltd., 24 Gilbert Street, London W1Y 1RJ, United Kingdom.

2. Annex III

Part A: Labelling:

-replace the name of the holder appearing on the labelling by Ares Serono (Europe) Ltd.

Part B: Package leaflet(s):

-replace the name appearing under the heading "holder of the marketing authorisation" by Ares Serono (Europe) Ltd., 24 Gilbert Street, London W1Y 1RJ, United Kingdom.

Article 3

1.The transfer referred to in Article 1 shall be authorised from 15 September 2001.

2.All the procedures resulting from this transfer shall be completed no later than the date of the Commission Decision.

Article 4

This Decision is addressed to ASTA Medica Aktiengesellschaft, An der Pikardie 10, 01227 Dresden, Deutschland and Ares Serono (Europe) Ltd., 24 Gilbert Street, London W1Y 1RJ, United Kingdom.

Done at Brussels, 20.03.2001

For the Commission
Erkki LIIKANEN
Member of the Commission